510(k) Summary

K082798

MedicaTech USA
50 Maxwell
Irvine , CA , 92618
Toll Free : +1 800 817 5030
Phone : +1 949 679 2881
FAX : +1 949 679 2882

OCT 2 8 2008

September 8, 2008
Contact: Ashraf Stefan , CEO

1. Identification of the Device:
   Proprietary-Trade Name: MAK 1500, MAK 2000, MAK 3000 Digital Diagnostic X-Ray System (STATIONARY).
   Classification Name: Stationary X-ray system,
   Product Codes Product Code 90 KPR and MQB
   Common/Usual Name: General purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: This notification is for a MODIFIED device. The device represents a variation of the tubehead mounting method described in our 510(k) number K080582.

3. Indications for Use (intended use) These digital X-Ray Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. Description of the Devices:
   The MAK 1500 employs a ceiling mounted tubehead/collimator combination made by Suinsa, the NOVA . The system has one digital panel inside the universal bucky in the chest stand. It employs the Suinsa NBS-2100 Universal Bucky. The MAK 2000 uses a conventional vertical column mount and adds a Suinsa NET-4100 table. The MAK 3000, like the MAK 1500, employs a ceiling mount and universal bucky in the chest stand and adds the Suinsa NET-4100 table with a digital panel mounted inside. The digital panel is the same one we supplied in K080582, manufactured by DRTech Corporation (K080064) and the software is also unchanged.

5. Safety and Effectiveness, comparison to predicate device. The results of bench and standards testing indicates that the new device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Medicatech USA
% Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

AUG - 9 2013

Re: K082798
Trade/Device Name: Model MAK 1500, MAK2000, MAK 3000 Digital Diagnostic X-Ray System (Stationary). (Digital Diagnostic X-Ray System)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: September 19, 2008
Received: October 2, 2008

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of October 28, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082798

Device Name: Model MAK 1500, MAK 2000, MAK 3000 Digital Diagnostic X-Ray System (STATIONARY). (Digital Diagnostic X-Ray Systems)

Indications For Use:

The MAK 1500, MAK 2000, MAK 3000 Digital Diagnostic X-Ray System (STATIONARY). (Digital Diagnostic X-Ray Systems) are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082798